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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Appellant : Yamaguchi, et al.  
App. No : 10/576,030  
Filed : April 13, 2006  
For : METHOD FOR PRODUCING  
SCYLLO-INOSITOL  
Examiner : Jonathan Lau  
Art Unit : 1623  
Conf No. : 2081

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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Appellants request review of the Final Rejection in the above-identified application. No amendments are being filed with this request. It is noted that the amendment submitted after Final of August 21, 2009 has been entered. Accordingly, claims 35-37 and 43 are pending.

Enclosed with this request is a Notice of Appeal.

**REASONS FOR REQUEST**

Review of the above-identified application is requested for the following reasons:

- A. **Claims 35-37 and 43 are not properly rejected under 35 U.S.C. § 103(a) because the references taken as a whole do not teach the claimed invention.**

The Examiner relies upon 6 references in the rejection of the claims as obvious: Merck (DE 3405663; machine translation and partial translation by Appellant submitted March 6, 2009), Weissbach, Mopper, Encyclopedia Britannica, Kiely, et al., and SIGMA-Aldrich

(Technical Information Bulletin AL-142). Taken as a whole, the references do not teach the claimed invention.

**Merck does not teach any of the elements of the invention**

The primary reference, **Merck**, teaches none of the method steps of the claimed invention as discussed in the After Final Amendment filed 8/21/09 from page 4, last paragraph to page 5, last paragraph.

In particular, Merck does not teach formation of a scyllo-inositol / boric acid complex. The Examiner asserts that one of ordinary skill in the art would know that Merck forms a scyllo-inositol /boric acid complex because Weissbach teaches a scyllo-inositol /boric acid complex (See Advisory Action, page 4, last two paragraphs and page 5, paragraph 1). However, Weissbach teaches a completely different procedure than Merck so it is not possible to rely upon Weissbach to assert that Merck teaches the claimed method, when Merck, in fact, discloses none of the method steps recited in Appellants' claims. Reasons for Appellants' position are provided in more detail in the response filed on 3/6/09, page 4, last three paragraphs to page 5, paragraph 5 and in the response filed 9/4/08, page 5, entire page to page 6, 1<sup>st</sup> full paragraph. In describing the method steps of Merck in the 3/6/09 and 9/4/08 responses, it is clear that Merck does not teach formation of scyllo-inositol / boric acid complex and does not teach the steps of the claimed method.

**Weissbach teach a different method to obtain the scyllo-inositol / boric acid intermediate and do not teach isolation of the final product by precipitation.**

**Weissbach** teaches the formation of a scyllo-inositol / boric acid complex and its isolation as precipitate relating to steps 1 and 2 of the method. However, Weissbach does not teach addition of any metal salt as set forth in claim 35 of the method of Appellants. Weissbach also does not teach the 4<sup>th</sup> step of adding ethanol or methanol to precipitate scyllo-inositol. The scyllo-inositol obtained after acidification of the scyllo-inositol / boric acid complex is concentrated by evaporation of the solvent (azeotropy) in Weissbach. Accordingly, Weissbach do not teach the method as claimed. See the discussion of Weissbach in the response filed on 9/4/08, page 6, 2<sup>nd</sup> and 3<sup>rd</sup> full paragraphs.

**Mopper does not teach any of the elements of the claimed invention**

The Examiner states that although neither Weissbach nor Merck teach precipitation of a scyllo-inositol / boric acid complex with a metal salt, Mopper teaches reaction of sugars with borate to form complexes by optimization of pH and salinity (Advisory Action, page 5, last paragraph)

Formation of a complex in solution is not equivalent to precipitation. **Mopper** teaches formation of sugar-borate complexes in solution, followed by separation by ion-exchange chromatography. Mopper do not teach a scyllo-inositol / boric acid complex and do not teach precipitation of any complex. Like Merck, Mopper does not teach any of the elements of the claimed invention.

**Encyclopedia Britannica does not demonstrate that chromatography, precipitation and azeotropy are interchangeable techniques**

The Examiner cites the **Encyclopedia Britannica** as showing that precipitation and chromatography are interchangeable. As discussed further below, these techniques are not used interchangeably by those skilled in the art. Accordingly Mopper's teaching on the use of an ion-exchange column is not equivalent to separation by precipitation and Mopper does not teach any of the elements of the claimed invention as also discussed in more detail in the After Final Amendment (8/21/09) on page 6, last two paragraphs.

**Kiely adds nothing to the teaching of Weissbach**

Kiely teaches that scyllo-inositol precipitates, which is known from Weissbach.

**B. The Examiner's position that techniques of precipitation, azeotropy and chromatography are equivalent is technically incorrect.**

The Examiner takes the position that various purification methods such as precipitation, azeotropy and chromatography are equivalent. However, these methods are not equivalent and would not be used interchangeably by one of ordinary skill in the art.

At some level, all purification methods have the common goal of enrichment of a desired product, but this does not mean that all such purification methods can be used interchangeably. One cannot use a method directed to separation of 2 liquids (azeotropy) instead of a method for formation of solid material from a liquid mixture (precipitation). Likewise, conditions for column chromatography (interaction of a compound in a mixture with column material by binding) is not the same as precipitation which involves a change of state of a substance from a solute to crystal/solid material (precipitation).

In the Advisory Action of 9/9/09, the Examiner asserts that azeotropy is equivalent to precipitation (page 5, lines 8-12). Appellants disagree as azeotropy relates to separation of liquids while precipitation relates to separation of a solid from a solution. Regarding the Examiner's statements on the ion-exchange and absorption chromatography and precipitation (see Final Office Action, page 6, second to last paragraph), while the "purpose" of ion-exchange chromatography, absorption chromatography and precipitation may be the same, the means and mechanism are very different. Accordingly, Mopper's teaching on the use of an ion-exchange column is not equivalent to separation by precipitation (see After Final response of 8/21/09, page 6, first full paragraph).

### **Summary**

Weissbach would appear to be the closest prior art. However, Weissbach teaches a different method of obtaining scyllo-inositol / boric acid precipitate that does not employ metal salts as recited in claim 35. Furthermore, Weissbach teaches isolation of the final scyllo-inositol (scyllitol) by azeotropy, not precipitation as per Appellants' invention. These deficiencies are not corrected by the remaining cited references, taken separately or together. Accordingly, the claimed invention cannot be obvious. Kiely does not add anything to the teaching of Weissbach. The remaining references do not relate to the method steps claimed for the reasons presented above and in the previous responses.

### **Conclusion**

In view of the foregoing arguments, Appellant respectfully requests that the rejection of these claims be withdrawn.

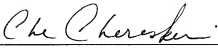
Application No.: 10/576,030  
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 20, 2009

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